SKRIPSI

KARAKTERISTIK KEJADIAN IKUTAN PASCAIMUNISASI (KIPI) SINOVAC DAN MODERNA *BOOSTER* DI FAKULTAS KEDOKTERAN UNIVERSITAS SRIWIJAYA

ALISSA RAHMA

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PROGRAM STUDI PENDIDIKAN DOKTER

FAKULTAS KEDOKTERAN

UNIVERSITAS SRIWIJAYA

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Diajukan untuk memenuhi salah satu syarat guna memeroleh gelar Sarjana Kedokteran (S.Ked)

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LAPORAN AKHIR SKRIPSI

Diajukan untuk melengkapi salah satu syarat memperoleh gelar Sarjana Kedokteran di Universitas Sriwijaya

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Karya tulis imiah berupa laporan akhir skripsi dengan judul "Karakteristik Kejadian Ikutan Pascaimunisasi (KIPI) Sinovac dan Moderna *Booster* di Fakultas Kedokteran Universitas Sriwijaya" telah dipertahankan di hadapan Tim Penguji Karya Tulis Ilmiah Program Studi Pendidikan Dokter Fakultas Kedokteran Universitas Sriwijaya pada tanggal 12 Januari 2022.

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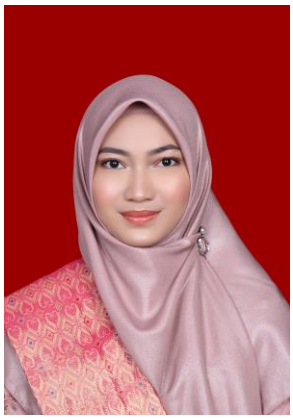

Palembang, 12 Januari 2022

Alissa Rahma

ABSTRAK

KARAKTERISTIK KEJADIAN IKUTAN PASCAIMUNISASI (KIPI) SINOVAC DAN MODERNA *BOOSTER* DI FAKULTAS KEDOKTERAN UNIVERSITAS SRIWIJAYA

(Alissa Rahma, Fakultas Kedokteran Universitas Sriwijaya, 95 halaman)

Latar Belakang: Kasus COVID-19 terus meningkat di seluruh dunia, vaksin menjadi salah satu cara untuk mencegah penyakit COVID-19. Semakin tingkat vaksinasi meningkat, masyarakat menjadi perhatian mengenai efek samping vaksin, yang disebut kejadian ikutan pascaimunisasi (KIPI). Penelitian ini bertujuan untuk mengetahui karakteristik KIPI Sinovac dan Moderna *booster* di FK UNSRI.

Metode: Jenis penelitian penelitian ini adalah deskriptif observasional menggunakan kuesioner yang diberikan secara langsung di FK UNSRI dan melalui *google form*. Penelitian ini dilaksanakan pada bulan November 2021—Desember 2021. Penelitian ini dibagi menjadi dua populasi yaitu yang divaksinasi Sinovac dan Moderna *booster*, dengan teknik *total sampling*.

Hasil: 690 responden sudah divaksinasi Sinovac dosis 1, 678 sudah divaksinasi Sinovac dosis 2, dan 352 sudah divaksinasi Moderna *booster*. Pada Sinovac dosis 1, gejala KIPI terbanyak adalah nyeri tekan, nyeri pada lengan yang disuntikkan, dan fatigue. Pada Sinovac dosis 2, gejala KIPI terbanyak adalah nyeri tekan, nyeri pada lengan yang disuntikkan, dan fatigue. Pada Moderna *booster*, gejala KIPI terbanyak adalah nyeri tekan, nyeri pada lengan yang disuntikkan, dan malaise.

Kesimpulan: Gejala KIPI Sinovac dan Moderna *booster* dapat sembuh dengan sendirinya dengan mayoritas lama gejala 1-2 hari bagi Sinovac dan 2-3 hari bagi Moderna booster. Reaksi serius pada vaksin Sinovac dan Moderna memiliki persentase sangat kecil.

Kata Kunci: KIPI, Efek Samping, Sinovac, CoronaVac, Moderna *booster*

ABSTRACT

CHARACTERISTICS ADVERSE EVENTS FOLLOWING IMMUNIZATION SINOVAC AND MODERNA BOOSTER IN FACULTY OF MEDICINE, SRIWIJAYA UNIVERSITY

(Alissa Rahma, Faculty of Medicine Sriwijaya University, 95 pages)

Background: COVID-19 cases continue to increase throughout the world, vaccines are one way to prevent COVID-19 disease. With increasing vaccination, people are becoming more concerned about the side effects of vaccines, which are known as adverse effects following immunization (AEFI). This study aims to determine the characteristics of AEFI Sinovac and Moderna booster in Faculty of Medicine, Sriwijaya University.

Method: This type of research is descriptive observational using a questionnaire that was given directly and through the google form. This research was conducted in November 2021—December 2021. This study was divided into two populations, namely those vaccinated with Sinovac and Moderna booster, using a total sampling technique.

Results: 690 respondents had been vaccinated with Sinovac dose 1, 678 had been vaccinated against Sinovac dose 2, and 352 had been vaccinated with Moderna booster. In Sinovac dose 1, the most common AEFI symptoms were tenderness, pain in the injected arm, and fatigue. In Sinovac dose 2, the most common AEFI symptoms were tenderness, pain in the injected arm, and fatigue. In Moderna booster, the most common AEFI symptoms are tenderness, pain in the injected arm, and malaise.

Conclusion: Symptoms of AEFI Sinovac and Moderna booster can heal by itself with the majority of symptoms lasting 1-2 days for Sinovac and 2-3 days for Moderna booster. Serious reactions to Sinovac and Moderna vaccines have a very small percentage.

Keywords: AEFI, Adverse Effects, Sinovac, CoronaVac, Moderna booster

RINGKASAN

KARAKTERISTIK KEJADIAN IKUTAN PASCAIMUNISASI (KIPI) SINOVAC DAN MODERNA *BOOSTER* DI FAKULTAS KEDOKTERAN UNIVERSITAS SRIWIJAYA

Karya tulis ilmiah berupa Skripsi, 11 Januari 2022

Alissa Rahma; dibimbin oleh Prof. dr. Eddy Mart Salim, SpPD, K-AI dan dr. Desi Oktariana, M.Biomed

Pendidikan Dokter Umum, Fakultas Kedokteran, Universitas Sriwijaya

95 halaman, 21 tabel, 12 gambar, 6 lampiran

Kasus COVID-19 terus meningkat di seluruh dunia, vaksin menjadi salah satu cara untuk mencegah penyakit COVID-19. Semakin tingkat vaksinasi meningkat, masyarakat menjadi perhatian mengenai efek samping vaksin, yang disebut kejadian ikutan pascaimunisasi (KIPI). Penelitian ini bertujuan untuk mengetahui karakteristik KIPI Sinovac dan Moderna *booster* di FK UNSRI. Jenis penelitian penelitian ini adalah deskriptif observasional menggunakan kuesioner yang diberikan secara langsung di FK UNSRI dan melalui *google form*. Penelitian ini dilaksanakan pada bulan November 2021—Desember 2021. Penelitian ini dibagi menjadi dua populasi yaitu yang divaksinasi Sinovac dan Moderna *booster*, dengan teknik *total sampling*. 690 responden sudah divaksinasi Sinovac dosis 1, 678 sudah divaksinasi Sinovac dosis 2, dan 352 sudah divaksinasi Moderna *booster*. Pada Sinovac dosis 1, gejala KIPI terbanyak adalah nyeri tekan, nyeri pada lengan yang disuntikkan, dan fatigue. Pada Sinovac dosis 2, gejala KIPI terbanyak adalah nyeri tekan, nyeri pada lengan yang disuntikkan, dan fatigue. Pada Moderna *booster*, gejala KIPI terbanyak adalah nyeri tekan, nyeri pada lengan yang disuntikkan, dan malaise. Gejala KIPI Sinovac dan Moderna *booster* dapat sembuh dengan sendirinya dengan mayoritas lama gejala 1-2 hari bagi Sinovac dan 2-3 hari bagi Moderna booster. Reaksi serius pada vaksin Sinovac dan Moderna memiliki persentase sangat kecil.

SUMMARY

CHARACTERISTICS ADVERSE EVENTS FOLLOWING IMMUNIZATION SINOVAC AND MODERNA BOOSTER IN FACULTY OF MEDICINE, SRIWIJAYA UNIVERSITY

Scientific paper in the form of Skripsi, 11 Januari 2022

Alissa Rahma; supervised by Prof. dr. Eddy Mart Salim, SpPD, K-AI and dr. Desi Oktariana, M.Biomed

Study Program of Medival Education, Faculty of Medicine, Sriwijaya University

95 pages, 21 tables, 12 pictures, 6 attachments

COVID-19 cases continue to increase throughout the world, vaccines are one way to prevent COVID-19 disease. With increasing vaccination, people are becoming more concerned about the side effects of vaccines, which are known as adverse effects following immunization (AEFI). This study aims to determine the characteristics of AEFI Sinovac and Moderna booster in Faculty of Medicine, Sriwijaya University. This type of research is descriptive observational using a questionnaire that was given directly and through the google form. This research was conducted in November 2021—December 2021. This study was divided into two populations, namely those vaccinated with Sinovac and Moderna booster, using a total sampling technique. 690 respondents had been vaccinated with Sinovac dose 1, 678 had been vaccinated against Sinovac dose 2, and 352 had been vaccinated with Moderna booster. In Sinovac dose 1, the most common AEFI symptoms were tenderness, pain in the injected arm, and fatigue. In Sinovac dose 2, the most common AEFI symptoms were tenderness, pain in the injected arm, and fatigue. In Moderna booster, the most common AEFI symptoms are tenderness, pain in the injected arm, and malaise. Symptoms of AEFI Sinovac and Moderna booster can heal by itself with the majority of symptoms lasting 1-2 days for Sinovac and 2-3 days for Moderna booster. Serious reactions to Sinovac and Moderna vaccines have a very small percentage.

KATA PENGANTAR

بِسْمِ اللَّهِ الرَّحْمَٰنِ الرَّحِيمِ

Segala puji bagi Allah yang Maha Esa, Tuhan yang Maha Baik lagi Maha Pemurah, Maha Penyayang lagi Maha Pengasih. Karena pertolongan-Nya, penulis dapat menyelesaikan laporan akhir skripsi yang berjudul **"Karakteristik Kejadian Ikutan Pascaimunisasi (KIPI) Sinovac dan Moderna *Booster* di Fakultas Kedokteran Universitas Sriwijaya"**. Saya bersaksi bahwa tidak ada tuhan yang berhak disembah selain Allah dan saya bersaksi bahwa Muhammad adalah hamba dan Rasul-Nya. Semoga shalawat dan salam tercurah kepada beliau, kepada nabi-nabi lainnya, keluarga mereka, dan orang-orang shalih.

Penulis mengucapkan terima kasih kepada semua pihak yang telah mendoakan, membimbing, memberikan bantuan, dan menyemangati penulis sehingga tugas ini dapat diselesaikan tepat waktu. Terima kasih banyak kepada Prof. dr. Eddy Mart Salim, SpPD, K-AI dan dr. Desi Oktariana, M.Biomed selaku dosen pembimbing atas bimbingan, ilmu, dan waktunya sehingga laporan akhir skripsi ini dapat diselesaikan. Terima kasih banyak kepada dr. Yuniza, Sp.PD, K-AI dan dr. Soilia Fertilita, M.Imun selaku dosen penguji atas bimbingan, ilmu, saran, dan masukannya kepada penulis. Terima kasih sebesar-besarnya kepada orangtua dan teman-teman yang selalu mendoakan, menyemangati, dan membantu penulis baik secara langsung maupun tidak langsung.

Penulis menyadari bahwa laporan usulan penelitian skripsi ini banyak kekurangan. Oleh karena itu, kritik dan saran dari pembaca sangat penulis harapkan. Akhir kata, semoga laporan ini dapat menambah ilmu pengetahuan dan dapat bermanfaat bagi pembaca.

Palembang, 12 Januari 2022

Alissa Rahma

DAFTAR ISI

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DAFTAR GAMBAR

DAFTAR LAMPIRAN

DAFTAR SINGKATAN

ARDS	: *Acute respiratory distress syndrome*
ACE-2	: *Angiotensin Converting Enzyme* 2
Ag	: Antigen
Adj	: Ajuvan
APC	: *Antigen Presenting Cell*
ARB	: *Angiotensin Receptor Blocker*
AS	: Amerika Serikat
BM	: *Bone marrow*
CDC	: *Centers for Disease Control and Prevention*
CFR	: *Case Fatality Rate*
COVID-19	: *Coronavirus Disease 2019*
CXCL-10	: *C-X-C motif chemokine ligand* 10
DC	: *Dendritic Cell*
DKI	: Daerah Khusus Ibukota
E	: *Envelope*
EUA	: *Emergency Use Authorization*
FDC	: *Follicular dendritic cell*
FK	: Fakultas Kedokteran Universitas Sriwijaya
GC	: *Germinal center*
IFN	: Interferon

Ig	: *Immunoglobulin*
KGB	: Kelenjar Getah Bening
LNP	: *Lipid Nanoparticle*
M	: *Membrane*
MHC	: *Major histocompatibility complex*
mRNA	: *messenger RNA*
N	: *Nucleocapsid*
Nab	: *Neutralizing antibody*
PAMP	: *patogen-associated molecular pattern*
PBMC	: *peripheral blood mononuclear cells*
PPOK	: Penyakit paru obstruktif kronik
PSBB	: Pembatasan Sosial Berskala Besar
PPKM	: Pemberlakuan Pembatasan Kegiatan Masyarakat
PRRs	: *Patoghen recognition receptors*
RBD	: *Receptor-binding domain*
RE	: Retikulum endoplasma
RNA	: *Ribonucleic Acid*
S	: *Spike*
SAE	: *serious adverse events*
SARS-CoV-2	: *severe acute respiratory syndrome coronavirus* 2
SIG	: *US government SARS-CoV-2 Interagency Group*
SOP	: Standar Operasional Prosedur

*ss*RNA	: *single-stranded* RNA
Tfh	: *T Follicular Helper*
Th	: *T-helper cell*
TNF	: *tumor necrosis factor*.
TSS	: *Toxic shock syndrome*
UNSRI	: Universitas Sriwijaya
VoI	: *variant of interest*
VoC	: *variant of concern*
WHO	: *World Health Organization*

BAB I
PENDAHULUAN

1.1. Latar Belakang

Coronavirus disease 2019 (COVID-19) adalah penyakit infeksi yang disebabkan oleh *severe acute respiratory syndrome coronavirus 2* (SARS-CoV-2), yang sebelumnya patogen ini dinamakan 2019-*novel coronavirus* (2019-nCOV).[1] Kasus COVID-19 terus meningkat di seluruh dunia, hingga 27 Agustus 2021 total kasus konfirmasi adalah 214,468,601 dengan 4,470,969 kematian (*Case Fatality Rate* (CFR) 2,1%) di 204 negara terjangkit.[2] Hingga 28 Agustus 2021, di Indonesia telah dilaporkan 4.066.404 orang terkonfirmasi positif COVID-19 dengan pertambahan 10.050 kasus pada hari ini, dan 131.372 total kematian (CFR 3,2%) terkait COVID-19.[3] Sementara di Kota Palembang, kasus konfirmasi bertambah 58 kasus dengan total 29.595 dan total kematian 1.106 orang.[4]

Pemerintah Indonesia telah mengeluarkan kebijakan-kebijakan untuk menekan penyebaran virus sejak munculnya kasus COVID-19 di Indonesia, seperti Pembatasan Sosial Berskala Besar (PSBB), PSBB transisi, Pemberlakuan Pembatasan Kegiatan Masyarakat (PPKM) darurat, hingga PPKM empat level. Langkah lainnya yang dilakukan pemerintah untuk menurunkan angka kesakitan dan kematian akibat COVID-19 dan mencapai kekebalan kelompok adalah vaksinasi COVID-19, yang dimulai pada tenaga medis pada tanggal 13 Januari 2021.

Vaksin COVID-19 akan menghasilkan kekebalan aktif yang didapat (*acquired active immunity*) terhadap SARS-CoV-2.[5] Terdapat 4 jenis vaksin COVID-19 yang sudah digunakan di Indonesia, yaitu Sinovac, AstraZeneca, Moderna, dan Pfizer. Pada vaksinasi tahap 1, Sinovac diberikan kepada tenaga kesehatan, tenaga penunjang, dan mahasiswa *co-assistant*. Tenaga kesehatan juga diberikan Moderna sebagai *booster* minimal 3 bulan setelah dosis kedua Sinovac

diberikan. Masyarakat yang masuk tahap 3 dan 4, mendapat vaksinasi dengan pendekatan kluster sesuai dengan ketersediaan vaksin.

Kejadian ikutan pascaimunisasi (KIPI) adalah suatu kejadian medis yang tidak diinginkan, terjadi setelah imunisasi dan tidak selalu memiliki hubungan sebab akibat dengan penggunaan vaksin.[6] *World Health Organization* (WHO) mengklasifikasikan KIPI menjadi lima, yaitu reaksi berhubungan dengan produk vaksin, reaksi terkait kualitas vaksin, reaksi berhubungan dengan kesalahan prosedur imunisasi, reaksi terkait kecemasaan imunisasi/*Immunization stress related response* (ISRR), dan kejadian koinsidensi.[7] Sebagian besar KIPI diamati dalam 1 hingga 3 hari pertama setelah vaksinasi dan sembuh setelahnya.[8] Penelitian mengenai gejala KIPI vaksin Sinovac pada tenaga kesehatan di rumah sakit rujukan Kota Padang, didapatkan gejala yang umum adalah mialgia (39,6%), fatigue (35,8%), dan sakit kepala (22,1%). Dilaporkan pula reaksi anafilaksis (0,4%).[9] Hasil uji klinis mengenai gejala keamanan vaksin Moderna, didapatkan gejala umum adalah nyeri lokal (83,7%), sakit kepala (63%), mialgia (59,6%), artralgia (44,8%), menggigil (43,4%), demam (14,8%), dan limfadenopati axilla (10,2%).[10] Surveilans di Ontario mendapatkan angka KIPI serius Moderna yang dilaporkan adalah 4,2 dari 100.000 dosis yang diberikan.[11] Berdasarkan 423 laporan miokarditis atau perikarditis, tingkat pelaporan kasar keseluruhan adalah 20,4 per satu juta dosis vaksin mRNA, Pfizer dan Moderna, yang diberikan.[11] Surveilans di Mexico dilaporkan 17.027 kasus KIPI (0,1% dosis yang diberikan) dengan 711 terkait Sinovac. Dari yang telah dilaporkan tersebut, terdapat 280 kasus serius KIPI dengan 51 kasus terkait Sinovac.[12]

Masyarakat Indonesia sudah menerima dua dosis vaksin COVID-19 (18,26%) pada tanggal 4 September 2021,[13] Meningkatkan cakupan vaksinasi COVID-19 untuk tujuan kekebalan kelompok merupakan hal penting. Disinformasi melalui media massa menyebabkan kecemasan yang cukup besar di antara masyarakat tentang keamanan vaksin. Karena hal tersebut dan sedikitnya penelitian tentang KIPI COVID-19 di Indonesia, khususnya kota Palembang, peneliti termotivasi untuk melakukan penelitian karakteristik kejadian ikutan

pascaimunisasi (KIPI) Sinovac dan Moderna *booster* di Fakultas Kedokteran Universitas Sriwijaya.

1.2. Rumusan Masalah

Bagaimana Karakteristik KIPI Sinovac dan Moderna *booster* di Fakultas Kedokteran Universitas Sriwijaya?

1.3. Tujuan Penelitian

1.3.1 Tujuan Umum

Mengetahui karakteristik KIPI Sinovac dan Moderna *booster* di Fakultas Kedokteran Universitas Sriwijaya.

1.3.2 Tujuan Khusus

1. Mengetahui karakteristik sosiodemografi responden, berupa usia, jenis kelamin, dan pekerjaan.
2. Mengetahui distribusi KIPI Sinovac dosis pertama dan kedua.
3. Mengetahui karakteristik KIPI Sinovac dosis pertama dan kedua berdasarkan jenis gejala dan lama gejala.
4. Mengetahui distribusi KIPI Moderna *booster*.
5. Mengetahui karakteristik KIPI Moderna *booster* berdasarkan jenis gejala dan lama gejala.

1.4. Manfaat Penelitian

1.4.1 Manfaat Teoritis

1. Penelitian ini dapat dijadikan bahan informasi mengenai karakteristik KIPI sinovac dan moderna *booster*.
2. Penelitian ini dapat berguna bagi penelitian selanjutnya tentang KIPI COVID-19.

1.4.2 Manfaat Kebijakan

1. Penelitian ini diperlukan untuk promosi dan edukasi kesehatan untuk mengendalikan penularan COVID-19 melalui vaksinasi sehingga *herd-immunity* dapat tercapai.
2. Menjadi data surveilans dan keamanan vaksin Sinovac dan Moderna.

1.4.3 Manfaat Subjek

Memberi pengetahuan kepada dosen, pegawai, dan mahasiswa Fakultas Kedokteran Universitas Sriwijaya mengenai Kejadian Ikutan Pascaimunisasi (KIPI) Sinovac dan Moderna.

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